

# State of Misconsin

#### **LEGISLATIVE REFERENCE BUREAU**

# RESEARCH APPENDIX PLEASE DO NOT REMOVE FROM DRAFTING FILE

Date Transfer Requested: 10/04/2013

(Per: CMH)

# Appendix A ... segment II

Appendix A The drafting file for LRB 13-0576 (used to create 13-3348) (Representative Nygren draft)

**Appendix B** <sup>™</sup> The drafting file for LRB 11–0330 (used to create 13–0576) (DOJ draft)

has been transferred to the drafting file for

**2013** LRB-3348

(Representative Nygren draft)



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# State of Misconsin 2013 - 2014 LEGISLATURE

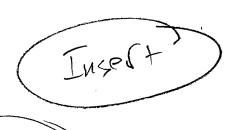
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# PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

(PZ)



regulation of prescription drugs.

AN ACT to renumber and amend 961.335 (1); to amend subchapter III (title) of chapter 961 [precedes 961.31]; and to create 66.0437, 440.255, 450.01 (23) (n), 450.01 (23) (o), 450.115, 961.32 (2) (e), 961.335 (1) (c) 1. and 2. and 961.337 of the statutes; relating to: programs for the disposal of drugs, including controlled substances, and certain medical or drug-related items, and the

### Analysis by the Legislative Reference Bureau

Under current law, a person may not, and it is often a crime to, deliver, receive, or possess certain drugs unless the person is a licensed pharmacist or other licensed practitioner or has a valid prescription for the drug.

Under this bill, the Department of Safety and Professional Service (DSPS) may authorize the operation of drug disposal programs in this state to receive, for destruction, drugs, including prescription drugs, controlled substances and controlled substance analogs, and certain medical and drug delivery devices (collectively, pharmaceutical items). DSPS may authorize a person to operate a drug disposal program if, among other things, the person demonstrates to the satisfaction of DSPS that the program's receipt of pharmaceutical items will comply with federal and state laws applicable to the transportation and delivery of pharmaceutical items. The bill requires a drug disposal program to adopt policies and procedures that describe in detail the place and manner of the program's operation, provide the

24-hour contact information for at least one person in this state who is responsible for the program, and ensure compliance with applicable state and federal laws. DSPS must approve the policies and procedures before a drug disposal program may begin operation.

The bill also provides that a city, village, town, or county (political subdivision) may operate or authorize another person to operate a drug disposal program within the political subdivision's borders. A drug disposal program that a political subdivision operates or authorizes must adopt policies and procedures similar to those described above, but the program need not obtain approval from DSPS. However, without DSPS approval, the program may not receive pharmaceutical items except by means of in-person delivery within the political subdivision's borders.

Finally, the bill authorizes a person who lawfully possesses a prescription drug, or the person's guardian, trustee, or personal representative, to grant written authorization to certain other persons to destroy the prescription drug. Under the bill, such a written authorization is only valid if the authorization satisfies certain conditions, including that the authorization describes the prescription drug with reasonable specificity and that the authorization and the prescription drug were obtained by the person authorized to destroy the prescription drug without the payment of money or something else of value.

For further information see the **state and local** fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 66.0437 of the statutes is created to read:

66.0437 Drug disposal programs. (1) In this section, "political subdivision"

has the meaning given in s. 440.255 (1) (e).

(2) A political subdivision may operate or authorize a person to operate a drug

disposal program as provided under s. 440.255 (3).

**Section 2.** 440.255 of the statutes is created to read:

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440.255 Drug disposal program. (1) DEFINITIONS. In this section:

- (a) "Controlled substance" has the meaning given in s. 961.01 (4).
- (b) "Controlled substance analog" has the meaning given in s. 961.01 (4m).

- (c) "Drug disposal program" means a program to receive pharmaceutical items and to recycle, destroy, or otherwise dispose of those items.
- (d) "Pharmaceutical item" means a drug, as defined in s. 450.01 (10); a prescription drug, as defined in s. 450.01 (20); a controlled substance or controlled substance analog; a device, as defined in 450.01 (6); or a hypodermic syringe, needle, or other object used for administering a drug.
  - (e) "Political subdivision" means a city, village, town, or county.
- (2) DEPARTMENT AUTHORIZATION TO OPERATE A DRUG DISPOSAL PROGRAM. (a) Except as provided under sub. (3), no person may receive pharmaceutical items pursuant to a drug disposal program unless the department grants written authorization for that program under par. (b) or the program is authorized under federal law.
- (b) The department may, without a hearing, grant written authorization to a person to operate a drug disposal program if all of the following conditions are satisfied:
- 1. The person adopts written policies and procedures that comply with sub. (5). The department shall review and either approve or disapprove in writing those policies and procedures. The department shall approve the policies and procedures if the department determines that the policies and procedures do not violate the requirements of this section or any other applicable federal or state law, and shall disapprove them otherwise. If the department disapproves the policies and procedures, the department shall state the reasons for that disapproval in writing to the person. At any time, the person may resubmit revised policies and procedures for the department's review and approval under this subdivision.
- 2. If the drug disposal program will receive pharmaceutical items in any manner other than the transfer of a pharmaceutical item in person to the program

- by a person that lawfully possesses the pharmaceutical item, the person demonstrates to the satisfaction of the department that those transfers will comply with any federal or state law applicable to the transportation and delivery of pharmaceutical items.
- (c) A person may not revise policies and procedures approved by the department under par. (b) 1. unless the department approves the revisions under par. (b) 1.
- (d) Any determination or action by the department under par. (b) or (c) is not subject to judicial review.
- (3) AUTHORIZATION BY A POLITICAL SUBDIVISION TO OPERATE A DRUG DISPOSAL PROGRAM. A political subdivision may operate or the governing body of a political subdivision may grant written authorization for a person to operate a drug disposal program only if all of the following apply:
- (a) The political subdivision or the authorized person operates the drug disposal program only within the boundaries of the political subdivision, except as provided under sub. (4).
  - (b) The applicable requirements under sub. (5) are satisfied.
- (c) The drug disposal program receives pharmaceutical items only by means of delivery in person by a person that lawfully possesses the pharmaceutical item, unless the drug disposal program is authorized under federal law to receive pharmaceutical items by other means.
- (4) MULTIJURISDICTIONAL DRUG DISPOSAL PROGRAM. A drug disposal program may operate within more than one political subdivision if the department authorizes that program under sub. (2), all political subdivisions within which the drug disposal

- program operates authorize that program under sub. (3), or the program is authorized under federal law.
- (5) OPERATION OF A DRUG DISPOSAL PROGRAM. (a) A person that operates a drug disposal program, except a drug disposal program that is authorized under federal law, shall establish and promptly update as appropriate written policies and procedures that do all of the following:
- 1. Describe in detail the manner in which the program operates, including an identification of the kinds of pharmaceutical items that may be received under the program, whether the program may receive controlled substances and controlled substance analogs, whether pharmaceutical items will be transferred by mail under the program, and the locations at which pharmaceutical items may be transferred in person under the program.
- 2. List the name, address, telephone number, and 24-hour contact information for one or more persons in this state who are responsible for the operation of the program.
- 3. Ensure compliance with chs. 450 and 961; with any applicable provision under chs. 287, 289, and 291 and s. 299.51 relating to medical waste, solid waste, or hazardous waste; and with any other applicable federal or state law.
- 4. If controlled substances or controlled substance analogs may be received under the program, ensure compliance with any applicable provision under 21 USC 801 to 865 relating to controlled substances or controlled substance analogs, ensure that delivery of any controlled substances complies with 21 USC 822 (g) and its implementing regulations, and ensure that any required permissions have been obtained from the federal drug enforcement administration.

- (b) 1. The policies and procedures for a drug disposal program authorized under sub. (2) and any changes to those policies and procedures are subject to review and approval under sub. (2) (b) 1.
- 2. Legal counsel for the political subdivision, or, at the discretion of the political subdivision, the department if the political subdivision's legal counsel is not an employee of the political subdivision, shall review and either approve or disapprove the policies and procedures for a drug disposal program implemented or authorized under sub. (3) and any changes to those policies and procedures. Legal counsel, or the department if appropriate, shall approve the policies and procedures or changes if it determines that the policies and procedures or changes do not violate the requirements of this section or any other applicable federal or state law, and shall disapprove them otherwise. Any approval under this subdivision shall be in writing. The political subdivision shall provide a copy of the approval and a copy of the policies and procedures or changes to the policies and procedures to the department.
- (c) The operation of a drug disposal program, including a drug disposal program that is authorized under federal law, shall immediately cease if a law enforcement officer, as defined in s. 165.85 (2) (c), a federal law enforcement officer, as defined in s. 175.40 (7) (a) 1., the department, or another federal or state agency notifies a designated contact person for the program that the program is in violation of any federal or state law enforceable by the officer, department, or other agency. That notification is not subject to judicial review. The program may resume operation only upon the program's receipt of written notice from the officer, department, or other agency that the program is no longer in violation of the federal or state law.
- (6) Transfer and receipt of pharmaceutical items. (a) Notwithstanding ss. 450.03 (1) and 450.11 (7) (g) and (h) and (9) (b), a person that lawfully possesses a

1 pharmaceutical item may transfer, and it is not a crime for such a person to transfer, 2 the pharmaceutical item to a drug disposal program if the program is authorized under sub. (2) or (3) or/under federal law.  $\Im$ (b) Notwithstanding s. 450.11 (7) (g) and (h) and (9) (b), a person may receive, 4 5 and it is not a crime for a person to possess, a pharmaceutical item pursuant to a drug 6 disposal program if the receipt or possession is within the scope of the program and the program is authorized under sub. (2) or (3) or under federal law or, if the receipt or possession is not within the scope of the program, the receipt/is inadvertent and 9 the program promptly notifies an appropriate law enforcement officer of the receipt 10 or possession and complies with any instructions the law enforcement officer provides. 11 12**SECTION 3.** 450.01 (23) (n) of the statutes is created to read: 13 450.01 (23) (n) The operation or implementation of a drug disposal program 14 that is authorized under s. 440.255 (2) or (3) or/under federal law or the possession 15 or delivery of a pharmaceutical item, as defined in s. 440.255 (1) (d), within the scope (16)of a drug disposal program that is authorized under s. 440.255 (2) or (3) or/under 17 federal law. 18 **Section 4.** 450.01 (23) (o) of the statutes is created to read: 19 450.01 (23) (o) The possession or delivery of a prescription drug within the 20 scope of a written authorization under s. 450.115 (3). 21 **SECTION 5.** 450.115 of the statutes is created to read: 22 450.115 Drug disposal programs and authorizations. (1) In this section: 23 (a) "Guardian" means the person named by the court under ch. 880, 2003 stats., 24 or ch. 48 or 54 that has the duty and authority of guardianship.

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- (b) "Personal representative" means an executor, administrator, or special administrator of a decedent's estate, a person legally authorized to perform substantially the same functions, or a successor to any of those persons.
- (c) "Trustee" means a person that holds in trust title to or power over property. "Trustee" includes an original, added, or successor trustee.
  - (d) "Ward" means a person for whom a guardian has been appointed.
- (2) Nothing in this chapter, or rules promulgated under this chapter, prohibits any of the following:
  - (a) The direct operation or implementation of a drug disposal program that is authorized under s. 440.255 (2) or (3) or under federal laws
  - (b) The transfer of a prescription drug by a person that lawfully possesses the prescription drug to a drug disposal program that is authorized under s. 440.255 (2) or (3) or under federal law and that accepts the prescription drug.
  - (c) Subject to sub. (4), the possession of a prescription drug under a written authorization described in sub. (3).
  - (3) (a) A guardian may grant written authorization to an adult who is related to the guardian's ward by blood, marriage, or adoption within the 3rd degree of kinship as computed under s. 990.001 (16), or to a domestic partner of the ward under ch. 770, for the disposal of a prescription drug that belongs to the ward.
  - (b) A personal representative or a trustee may grant written authorization to an adult beneficiary, as defined in s. 701.20 (2) (b), of the estate or trust for the disposal of a prescription drug that belongs to the estate or trust.
- (c) A person who is a competent adult may grant written authorization to that person's domestic partner under ch. 770 or to another adult who is related to that person by blood, marriage, or adoption within the 3rd degree of kinship as computed las defined in s. 440. 255 (1) (4);

705 defined in 5.440.255 (1)(a)

1	under s. 990.001 (16), for the disposal of a prescription drug that lawfully belongs to
2	that person.
3	(4) A written authorization under sub. (3) is valid only to the extent permitted
4	under federal law and only if all of the following conditions are satisfied:
5	(a) The authorization describes with reasonable specificity each prescription
6	drug that is to be disposed of.
7	(b) The authorization is in the physical possession of the person authorized to
8	dispose of the prescription drug and each prescription drug described in the
9	authorization is, within 24 hours after the authorization is signed by the person
10	granting the authorization, transferred to a drug disposal program under s. 440.255
11	or otherwise lawfully disposed of.
12	(c) The authorization and each prescription drug to be disposed of were
13	obtained without consideration.
14	SECTION 6. Subchapter III (title) of chapter 961 [precedes 961.31] of the
15	statutes is amended to read:
16	CHAPTER 961
17	SUBCHAPTER III
18	REGULATION OF MANUFACTURE,
19	DISTRIBUTION AND, DISPENSING,
20	AND POSSESSION OF CONTROLLED
21	SUBSTANCES
22	SECTION 7. 961.32 (2) (e) of the statutes is created to read:
23	961.32 (2) (e) A person actively engaged in the direct operation or
24	implementation of a drug disposal program that is authorized under s. 440.255 (2)
25	or (3) or under federal law.
Market	(1) of under lederal law.  (1) (a) (b) (c) (c) (c) (d)

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Section 8.	961.335 (1)	of the statu	tes is renumber	ed 961.335	(1) (a) and
amended to read:					

961.335 (1) (a) Upon application the controlled substances board may issue a permit authorizing a person to manufacture, obtain, possess, use, administer, or dispense a controlled substance for purposes of scientific research, instructional activities, chemical analysis, or other special uses, without restriction because of enumeration. No

- (b) Except as provide in par. (c), no person shall may engage in any such activity described under par. (a) without a permit issued under this section, except that an.
- (c) 3. An individual may be who is designated and authorized to receive the a permit under this section for a college or university department, research unit, or similar administrative organizational unit, and students, laboratory technicians, research specialists, or chemical analysts under his or her supervision, may be permitted possession and use of controlled substances for these purposes, without obtaining an individual additional permit issued under this section, possess and use a controlled substance, for the purposes authorized in the permit received for the department or unit.

**SECTION 9.** 961.335 (1) (c) 1. and 2. of the statutes are created to read:

961.335 (1) (c) 1. A person who is actively engaged in the direct operation or implementation of a drug disposal program that is authorized under s. 440.255 (2) or (3) or under federal law may, without a permit issued under this section, obtain 27 or possess a controlled substance for the purposes of operating and implementing the drug disposal program.

1 as defined in s. 440.255(1)(4);

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2. A person who is authorized under federal law to dispose of a controlled substance may, without a permit issued under this section, possess the controlled substance for the purpose of disposing of the controlled substance.

SECTION 10. 961.337 of the statutes is created to read:

961.337 Drug disposal programs. Nothing in this chapter, or rules promulgated under this chapter, prohibits any of the following:

- (1) The direct operation or implementation of a drug disposal program that is authorized under s. 440.255 (2) or (3) or under federal law
- (2) The transfer by the ultimate user, or by another person that lawfully possesses the controlled substance or controlled substance analog, of a controlled substance or controlled substance analog to a drug disposal program that has been authorized under s. 440.255 (2) or (3) or under federal law and that accepts the controlled substance or controlled substance analog.

#### SECTION 11. Effective date.

(1) This act takes effect on the first day of the 4th month beginning after publication.

1 as defined in 5.440.255 (1) (4) }

17 (END)

is authorized

1 2 00 defined in 5, 440, 26>(1)(9)

#### 2013-2014 DRAFTING INSERT FROM THE LEGISLATIVE REFERENCE BUREAU

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1	INSERT 2-7
2	(a) "Authorized under federal law" means permitted under 21 USC 801 to 971
3	or 21 CFR 1300 to 1321.
4	END INSERT 2–7

#### Barman, Mike

From:

Malcore, Jennifer

Sent:

Tuesday, September 10, 2013 9:06 AM

To:

Gallagher, Michael

Subject:

FW: Draft review: LRB -0576/P2 Topic: Drug disposal program

Attachments:

13-0576\_P2.pdf

Michael,

Could you please send a version to be jacketed of this legislation to the Nygren office?

Let me know if you have any questions.

Thank you,

#### Jennifer Malcore

Office of State Representative John Nygren Co-Chair , Joint Committee on Finance 89<sup>th</sup> Assembly District 309 East, State Capitol 608.266.2344

From: Rinehart, Mark W. [mailto:RinehartMW@DOJ.STATE.WI.US]

Sent: Monday, September 09, 2013 5:01 PM

To: Malcore, Jennifer

Subject: FW: Draft review: LRB -0576/P2 Topic: Drug disposal program

Hello Jennifer,

I think if you forward this email string to LRB, they'll send you a version to be jacketed. If you have any problems, let me know and I'll contact them.

From: LRB.Legal [mailto:LRB-LegalServices@legis.wisconsin.gov]

**Sent:** Wednesday, May 29, 2013 2:54 PM

To: Rinehart, Mark W.

Subject: Draft review: LRB -0576/P2 Topic: Drug disposal program

Following is the PDF version of draft LRB -0576/P2.

#### Barman, Mike

From:

Gallagher, Michael

Sent:

Tuesday, September 10, 2013 9:36 AM

To:

LRB.Legal

Subject:

-0576

Hello front desk: Could you do the following for me on this draft?

 $\sqrt{1}$ . Print the attached e-mail and attachment for the file.

/ 2. Print the request sheet (I have updated the request with respect to the requester—Nygren replaces DOJ).

3. Pull the guts.

 $\checkmark$ 4. Mark the draft as a /1 (current draft is a /P2). No other changes to the draft.

√ 5. Put the draft and guts in editing to go out today.

6. Once the /1 is ready, have it jacketed for introduction per the attached e-mail.

Thanks very much. E-mail or call my cell if you have any questions. I already pulled the electronic file and forwarded it to editing.

Mike



FW: Draft review: LRB -0576/P2...

#### Michael P. Gallagher

**Legislative Attorney** Wisconsin Legislative Reference Bureau 1 East Main Street, Suite 200 P.O. Box 2037 Madison, WI 53701-2037 (608) 267-7511 michael.gallagher@legis.wisconsin.gov



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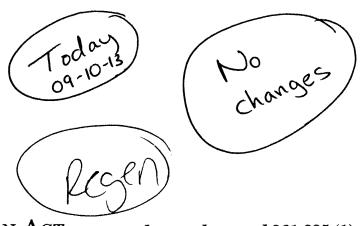
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# State of Misconsin 2013 - 2014 LEGISLATURE



PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION



AN ACT to renumber and amend 961.335 (1); to amend subchapter III (title) of chapter 961 [precedes 961.31]; and to create 66.0437, 440.255, 450.01 (23) (n), 450.01 (23) (o), 450.115, 961.32 (2) (e), 961.335 (1) (c) 1. and 2. and 961.337 of the statutes; relating to: programs for the disposal of drugs, including controlled substances, and certain medical or drug-related items, and the regulation of prescription drugs.

#### Analysis by the Legislative Reference Bureau

Under current law, a person may not, and it is often a crime to, deliver, receive, or possess certain drugs unless the person is a licensed pharmacist or other licensed practitioner or has a valid prescription for the drug.

Under this bill, the Department of Safety and Professional Service (DSPS) may authorize the operation of drug disposal programs in this state to receive, for destruction, drugs, including prescription drugs, controlled substances and controlled substance analogs, and certain medical and drug delivery devices (collectively, pharmaceutical items). DSPS may authorize a person to operate a drug disposal program if, among other things, the person demonstrates to the satisfaction of DSPS that the program's receipt of pharmaceutical items will comply with federal and state laws applicable to the transportation and delivery of pharmaceutical items. The bill requires a drug disposal program to adopt policies and procedures that describe in detail the place and manner of the program's operation, provide the

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24-hour contact information for at least one person in this state who is responsible for the program, and ensure compliance with applicable state and federal laws. DSPS must approve the policies and procedures before a drug disposal program may begin operation.

The bill also provides that a city, village, town, or county (political subdivision) may operate or authorize another person to operate a drug disposal program within the political subdivision's borders. A drug disposal program that a political subdivision operates or authorizes must adopt policies and procedures similar to those described above, but the program need not obtain approval from DSPS. However, without DSPS approval, the program may not receive pharmaceutical items except by means of in-person delivery within the political subdivision's borders.

Finally, the bill authorizes a person who lawfully possesses a prescription drug, or the person's guardian, trustee, or personal representative, to grant written authorization to certain other persons to destroy the prescription drug. Under the bill, such a written authorization is only valid if the authorization satisfies certain conditions, including that the authorization describes the prescription drug with reasonable specificity and that the authorization and the prescription drug were obtained by the person authorized to destroy the prescription drug without the payment of money or something else of value.

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

# The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

**SECTION 1.** 66.0437 of the statutes is created to read:

66.0437 Drug disposal programs. (1) In this section, "political subdivision" has the meaning given in s. 440.255 (1) (e).

(2) A political subdivision may operate or authorize a person to operate a drug disposal program as provided under s. 440.255 (3).

**SECTION 2.** 440.255 of the statutes is created to read:

440.255 Drug disposal program. (1) DEFINITIONS. In this section:

- (a) "Authorized under federal law" means permitted under 21 USC 801 to 971 or 21 CFR 1300 to 1321.
  - (am) "Controlled substance" has the meaning given in s. 961.01 (4).

- (b) "Controlled substance analog" has the meaning given in s. 961.01 (4m).
- (c) "Drug disposal program" means a program to receive pharmaceutical items and to recycle, destroy, or otherwise dispose of those items.
  - (d) "Pharmaceutical item" means a drug, as defined in s. 450.01 (10); a prescription drug, as defined in s. 450.01 (20); a controlled substance or controlled substance analog; a device, as defined in 450.01 (6); or a hypodermic syringe, needle, or other object used for administering a drug.
    - (e) "Political subdivision" means a city, village, town, or county.
  - (2) DEPARTMENT AUTHORIZATION TO OPERATE A DRUG DISPOSAL PROGRAM. (a) Except as provided under sub. (3), no person may receive pharmaceutical items pursuant to a drug disposal program unless the department grants written authorization for that program under par. (b) or the program is authorized under federal law.
  - (b) The department may, without a hearing, grant written authorization to a person to operate a drug disposal program if all of the following conditions are satisfied:
  - 1. The person adopts written policies and procedures that comply with sub. (5). The department shall review and either approve or disapprove in writing those policies and procedures. The department shall approve the policies and procedures if the department determines that the policies and procedures do not violate the requirements of this section or any other applicable federal or state law, and shall disapprove them otherwise. If the department disapproves the policies and procedures, the department shall state the reasons for that disapproval in writing to the person. At any time, the person may resubmit revised policies and procedures for the department's review and approval under this subdivision.

- 2. If the drug disposal program will receive pharmaceutical items in any manner other than the transfer of a pharmaceutical item in person to the program by a person that lawfully possesses the pharmaceutical item, the person demonstrates to the satisfaction of the department that those transfers will comply with any federal or state law applicable to the transportation and delivery of pharmaceutical items.
- (c) A person may not revise policies and procedures approved by the department under par. (b) 1. unless the department approves the revisions under par. (b) 1.
- (d) Any determination or action by the department under par. (b) or (c) is not subject to judicial review.
- (3) AUTHORIZATION BY A POLITICAL SUBDIVISION TO OPERATE A DRUG DISPOSAL PROGRAM. A political subdivision may operate or the governing body of a political subdivision may grant written authorization for a person to operate a drug disposal program only if all of the following apply:
- (a) The political subdivision or the authorized person operates the drug disposal program only within the boundaries of the political subdivision, except as provided under sub. (4).
  - (b) The applicable requirements under sub. (5) are satisfied.
- (c) The drug disposal program receives pharmaceutical items only by means of delivery in person by a person that lawfully possesses the pharmaceutical item, unless the drug disposal program is authorized under federal law to receive pharmaceutical items by other means.
- (4) MULTIJURISDICTIONAL DRUG DISPOSAL PROGRAM. A drug disposal program may operate within more than one political subdivision if the department authorizes that

- program under sub. (2), all political subdivisions within which the drug disposal program operates authorize that program under sub. (3), or the program is authorized under federal law.
  - (5) OPERATION OF A DRUG DISPOSAL PROGRAM. (a) A person that operates a drug disposal program, except a drug disposal program that is authorized under federal law, shall establish and promptly update as appropriate written policies and procedures that do all of the following:
  - 1. Describe in detail the manner in which the program operates, including an identification of the kinds of pharmaceutical items that may be received under the program, whether the program may receive controlled substances and controlled substance analogs, whether pharmaceutical items will be transferred by mail under the program, and the locations at which pharmaceutical items may be transferred in person under the program.
  - 2. List the name, address, telephone number, and 24-hour contact information for one or more persons in this state who are responsible for the operation of the program.
  - 3. Ensure compliance with chs. 450 and 961; with any applicable provision under chs. 287, 289, and 291 and s. 299.51 relating to medical waste, solid waste, or hazardous waste; and with any other applicable federal or state law.
  - (b) 1. The policies and procedures for a drug disposal program authorized under sub. (2) and any changes to those policies and procedures are subject to review and approval under sub. (2) (b) 1.
  - 2. Legal counsel for the political subdivision, or, at the discretion of the political subdivision, the department if the political subdivision's legal counsel is not an employee of the political subdivision, shall review and either approve or disapprove

- the policies and procedures for a drug disposal program implemented or authorized under sub. (3) and any changes to those policies and procedures. Legal counsel, or the department if appropriate, shall approve the policies and procedures or changes if it determines that the policies and procedures or changes do not violate the requirements of this section or any other applicable federal or state law, and shall disapprove them otherwise. Any approval under this subdivision shall be in writing. The political subdivision shall provide a copy of the approval and a copy of the policies and procedures or changes to the policies and procedures to the department.
- (c) The operation of a drug disposal program, including a drug disposal program that is authorized under federal law, shall immediately cease if a law enforcement officer, as defined in s. 165.85 (2) (c), a federal law enforcement officer, as defined in s. 175.40 (7) (a) 1., the department, or another federal or state agency notifies a designated contact person for the program that the program is in violation of any federal or state law enforceable by the officer, department, or other agency. That notification is not subject to judicial review. The program may resume operation only upon the program's receipt of written notice from the officer, department, or other agency that the program is no longer in violation of the federal or state law.
- (6) Transfer and receipt of Pharmaceutical Items. (a) Notwithstanding ss. 450.03 (1) and 450.11 (7) (g) and (h) and (9) (b), a person that lawfully possesses a pharmaceutical item may transfer, and it is not a crime for such a person to transfer, the pharmaceutical item to a drug disposal program if the program is authorized under sub. (2) or (3) or is authorized under federal law.
- (b) Notwithstanding s. 450.11 (7) (g) and (h) and (9) (b), a person may receive, and it is not a crime for a person to possess, a pharmaceutical item pursuant to a drug disposal program if the receipt or possession is within the scope of the program and

the program is authorized under sub. (2) or (3) or is authorized under federal law or,
if the receipt or possession is not within the scope of the program, the receipt or
possession is inadvertent and the program promptly notifies an appropriate law
enforcement officer of the receipt or possession and complies with any instructions
the law enforcement officer provides.
SECTION 3. 450.01 (23) (n) of the statutes is created to read:
450.01 (23) (n) The operation or implementation of a drug disposal program
that is authorized under s. 440.255 (2) or (3) or is authorized under federal law, as
defined in s. 440.255 (1) (a), or the possession or delivery of a pharmaceutical item,
as defined in s. 440.255 (1) (d), within the scope of a drug disposal program that is
authorized under s. 440.255 (2) or (3) or is authorized under federal law.
SECTION 4. 450.01 (23) (o) of the statutes is created to read:
450.01 (23) (o) The possession or delivery of a prescription drug within the
scope of a written authorization under s. 450.115 (3).
SECTION 5. 450.115 of the statutes is created to read:
450.115 Drug disposal programs and authorizations. (1) In this section:
(a) "Guardian" means the person named by the court under ch. 880, 2003 stats.,
or ch. 48 or 54 that has the duty and authority of guardianship.
(b) "Personal representative" means an executor, administrator, or special
administrator of a decedent's estate, a person legally authorized to perform
substantially the same functions, or a successor to any of those persons.
(c) "Trustee" means a person that holds in trust title to or power over property.
"Trustee" includes an original, added, or successor trustee.

(d) "Ward" means a person for whom a guardian has been appointed.

- (2) Nothing in this chapter, or rules promulgated under this chapter, prohibits any of the following:
- (a) The direct operation or implementation of a drug disposal program that is authorized under s. 440.255 (2) or (3) or is authorized under federal law, as defined in s. 440.255 (1) (a).
- (b) The transfer of a prescription drug by a person that lawfully possesses the prescription drug to a drug disposal program that is authorized under s. 440.255 (2) or (3) or is authorized under federal law, as defined in s. 440.255 (1) (a), and that accepts the prescription drug.
- (c) Subject to sub. (4), the possession of a prescription drug under a written authorization described in sub. (3).
- (3) (a) A guardian may grant written authorization to an adult who is related to the guardian's ward by blood, marriage, or adoption within the 3rd degree of kinship as computed under s. 990.001 (16), or to a domestic partner of the ward under ch. 770, for the disposal of a prescription drug that belongs to the ward.
- (b) A personal representative or a trustee may grant written authorization to an adult beneficiary, as defined in s. 701.20 (2) (b), of the estate or trust for the disposal of a prescription drug that belongs to the estate or trust.
- (c) A person who is a competent adult may grant written authorization to that person's domestic partner under ch. 770 or to another adult who is related to that person by blood, marriage, or adoption within the 3rd degree of kinship as computed under s. 990.001 (16), for the disposal of a prescription drug that lawfully belongs to that person.
- (4) A written authorization under sub. (3) is valid only to the extent permitted under federal law and only if all of the following conditions are satisfied:

1	(a) The authorization describes with reasonable specificity each prescription
2	drug that is to be disposed of.
3	(b) The authorization is in the physical possession of the person authorized to
4	dispose of the prescription drug and each prescription drug described in the
5	authorization is, within 24 hours after the authorization is signed by the person
6	granting the authorization, transferred to a drug disposal program under s. 440.255
7	or otherwise lawfully disposed of.
8	(c) The authorization and each prescription drug to be disposed of were
9	obtained without consideration.
10	SECTION 6. Subchapter III (title) of chapter 961 [precedes 961.31] of the
11	statutes is amended to read:
12	CHAPTER 961
13	SUBCHAPTER III
14	REGULATION OF MANUFACTURE,
15	DISTRIBUTION AND, DISPENSING,
16	AND POSSESSION OF CONTROLLED
17	SUBSTANCES
18	SECTION 7. 961.32 (2) (e) of the statutes is created to read:
19	961.32 (2) (e) A person actively engaged in the direct operation or
20	implementation of a drug disposal program that is authorized under s. 440.255 (2)
21	or (3) or is authorized under federal law, as defined in s. 440.255 (1) (a).
22	<b>SECTION 8.</b> 961.335 (1) of the statutes is renumbered 961.335 (1) (a) and
23	amended to read:
24	961.335 (1) (a) Upon application the controlled substances board may issue a
25	permit authorizing a person to manufacture, obtain, possess, use, administer, or

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1	dispense a controlled substance for purposes of scientific research, instructional
2	activities, chemical analysis, or other special uses, without restriction because of
3	enumeration. No
4	(b) Except as provide in par. (c), no person shall may engage in any such activity
5	described under par. (a) without a permit issued under this section, except that an
6	(c) 3. An individual may be who is designated and authorized to receive the a
7	permit under this section for a college or university department, research unit, or
8	similar administrative organizational unit, and students, laboratory technicians,
9	research specialists, or chemical analysts under his or her supervision, may be
10	permitted possession and use of controlled substances for these purposes, without
11	obtaining an individual additional permit issued under this section, possess and use
12	a controlled substance, for the purposes authorized in the permit received for the
13	department or unit.
14	SECTION 9. 961.335 (1) (c) 1. and 2. of the statutes are created to read:
15	961.335 (1) (c) 1. A person who is actively engaged in the direct operation or
16	implementation of a drug disposal program that is authorized under s. 440.255 (2)
17	or (3) or is authorized under federal law, as defined in s. 440.255 (1) (a), may, without
18	a permit issued under this section, obtain or possess a controlled substance for the
19	purposes of operating and implementing the drug disposal program.
20	2. A person who is permitted under federal law to dispose of a controlled
21	substance may, without a permit issued under this section, possess the controlled
22	substance for the purpose of disposing of the controlled substance.
23	SECTION 10. 961.337 of the statutes is created to read:

961.337 Drug disposal programs. Nothing in this chapter, or rules

promulgated under this chapter, prohibits any of the following:

publication.

(1) The direct operation or implementation of a drug disposal program that is
authorized under s. 440.255 (2) or (3) or is authorized under federal law, as defined
in s. 440.255 (1) (a).
(2) The transfer by the ultimate user, or by another person that lawfully
possesses the controlled substance or controlled substance analog, of a controlled
substance or controlled substance analog to a drug disposal program that has been
authorized under s. 440.255 (2) or (3) or is authorized under federal law, as defined
in s. 440.255 (1) (a), and that accepts the controlled substance or controlled substance
analog.
SECTION 11. Effective date.
(1) This act takes effect on the first day of the 4th month beginning after

(END)



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# State of Misconsin 2013 - 2014 LEGISLATURE



## **2013 BILL**

AN ACT to renumber and amend 961.335 (1); to amend subchapter III (title) of chapter 961 [precedes 961.31]; and to create 66.0437, 440.255, 450.01 (23) (n), 450.01 (23) (o), 450.115, 961.32 (2) (e), 961.335 (1) (c) 1. and 2. and 961.337 of the statutes; relating to: programs for the disposal of drugs, including controlled substances, and certain medical or drug-related items, and the regulation of prescription drugs.

### Analysis by the Legislative Reference Bureau

Under current law, a person may not, and it is often a crime to, deliver, receive, or possess certain drugs unless the person is a licensed pharmacist or other licensed practitioner or has a valid prescription for the drug.

Under this bill, the Department of Safety and Professional Service (DSPS) may authorize the operation of drug disposal programs in this state to receive, for destruction, drugs, including prescription drugs, controlled substances and controlled substance analogs, and certain medical and drug delivery devices (collectively, pharmaceutical items). DSPS may authorize a person to operate a drug disposal program if, among other things, the person demonstrates to the satisfaction of DSPS that the program's receipt of pharmaceutical items will comply with federal and state laws applicable to the transportation and delivery of pharmaceutical items. The bill requires a drug disposal program to adopt policies and procedures that describe in detail the place and manner of the program's operation, provide the

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24—hour contact information for at least one person in this state who is responsible for the program, and ensure compliance with applicable state and federal laws. DSPS must approve the policies and procedures before a drug disposal program may begin operation.

The bill also provides that a city, village, town, or county (political subdivision) may operate or authorize another person to operate a drug disposal program within the political subdivision's borders. A drug disposal program that a political subdivision operates or authorizes must adopt policies and procedures similar to those described above, but the program need not obtain approval from DSPS. However, without DSPS approval, the program may not receive pharmaceutical items except by means of in-person delivery within the political subdivision's borders.

Finally, the bill authorizes a person who lawfully possesses a prescription drug, or the person's guardian, trustee, or personal representative, to grant written authorization to certain other persons to destroy the prescription drug. Under the bill, such a written authorization is only valid if the authorization satisfies certain conditions, including that the authorization describes the prescription drug with reasonable specificity and that the authorization and the prescription drug were obtained by the person authorized to destroy the prescription drug without the payment of money or something else of value.

For further information see the **state and local** fiscal estimate, which will be printed as an appendix to this bill.

# The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 66.0437 of the statutes is created to read:

66.0437 Drug disposal programs. (1) In this section, "political subdivision"

has the meaning given in s. 440.255 (1) (e).

(2) A political subdivision may operate or authorize a person to operate a drug disposal program as provided under s. 440.255 (3).

SECTION 2. 440.255 of the statutes is created to read:

440.255 Drug disposal program. (1) DEFINITIONS. In this section:

(a) "Authorized under federal law" means permitted under 21 USC 801 to 971 or 21 CFR 1300 to 1321.

(am) "Controlled substance" has the meaning given in s. 961.01 (4).

- (b) "Controlled substance analog" has the meaning given in s. 961.01 (4m).
- (c) "Drug disposal program" means a program to receive pharmaceutical items and to recycle, destroy, or otherwise dispose of those items.
  - (d) "Pharmaceutical item" means a drug, as defined in s. 450.01 (10); a prescription drug, as defined in s. 450.01 (20); a controlled substance or controlled substance analog; a device, as defined in 450.01 (6); or a hypodermic syringe, needle, or other object used for administering a drug.
    - (e) "Political subdivision" means a city, village, town, or county.
  - (2) Department authorization to operate a drug disposal program. (a) Except as provided under sub. (3), no person may receive pharmaceutical items pursuant to a drug disposal program unless the department grants written authorization for that program under par. (b) or the program is authorized under federal law.
  - (b) The department may, without a hearing, grant written authorization to a person to operate a drug disposal program if all of the following conditions are satisfied:
  - 1. The person adopts written policies and procedures that comply with sub. (5). The department shall review and either approve or disapprove in writing those policies and procedures. The department shall approve the policies and procedures if the department determines that the policies and procedures do not violate the requirements of this section or any other applicable federal or state law, and shall disapprove them otherwise. If the department disapproves the policies and procedures, the department shall state the reasons for that disapproval in writing to the person. At any time, the person may resubmit revised policies and procedures for the department's review and approval under this subdivision.

- 2. If the drug disposal program will receive pharmaceutical items in any manner other than the transfer of a pharmaceutical item in person to the program by a person that lawfully possesses the pharmaceutical item, the person demonstrates to the satisfaction of the department that those transfers will comply with any federal or state law applicable to the transportation and delivery of pharmaceutical items.
- (c) A person may not revise policies and procedures approved by the department under par. (b) 1. unless the department approves the revisions under par. (b) 1.
- (d) Any determination or action by the department under par. (b) or (c) is not subject to judicial review.
- (3) AUTHORIZATION BY A POLITICAL SUBDIVISION TO OPERATE A DRUG DISPOSAL PROGRAM. A political subdivision may operate or the governing body of a political subdivision may grant written authorization for a person to operate a drug disposal program only if all of the following apply:
- (a) The political subdivision or the authorized person operates the drug disposal program only within the boundaries of the political subdivision, except as provided under sub. (4).
  - (b) The applicable requirements under sub. (5) are satisfied.
- (c) The drug disposal program receives pharmaceutical items only by means of delivery in person by a person that lawfully possesses the pharmaceutical item, unless the drug disposal program is authorized under federal law to receive pharmaceutical items by other means.
- (4) MULTIJURISDICTIONAL DRUG DISPOSAL PROGRAM. A drug disposal program may operate within more than one political subdivision if the department authorizes that

- program under sub. (2), all political subdivisions within which the drug disposal program operates authorize that program under sub. (3), or the program is authorized under federal law.
- (5) OPERATION OF A DRUG DISPOSAL PROGRAM. (a) A person that operates a drug disposal program, except a drug disposal program that is authorized under federal law, shall establish and promptly update as appropriate written policies and procedures that do all of the following:
- 1. Describe in detail the manner in which the program operates, including an identification of the kinds of pharmaceutical items that may be received under the program, whether the program may receive controlled substances and controlled substance analogs, whether pharmaceutical items will be transferred by mail under the program, and the locations at which pharmaceutical items may be transferred in person under the program.
- 2. List the name, address, telephone number, and 24-hour contact information for one or more persons in this state who are responsible for the operation of the program.
- 3. Ensure compliance with chs. 450 and 961; with any applicable provision under chs. 287, 289, and 291 and s. 299.51 relating to medical waste, solid waste, or hazardous waste; and with any other applicable federal or state law.
- (b) 1. The policies and procedures for a drug disposal program authorized under sub. (2) and any changes to those policies and procedures are subject to review and approval under sub. (2) (b) 1.
- 2. Legal counsel for the political subdivision, or, at the discretion of the political subdivision, the department if the political subdivision's legal counsel is not an employee of the political subdivision, shall review and either approve or disapprove

the policies and procedures for a drug disposal program implemented or authorized under sub. (3) and any changes to those policies and procedures. Legal counsel, or the department if appropriate, shall approve the policies and procedures or changes if it determines that the policies and procedures or changes do not violate the requirements of this section or any other applicable federal or state law, and shall disapprove them otherwise. Any approval under this subdivision shall be in writing. The political subdivision shall provide a copy of the approval and a copy of the policies and procedures or changes to the policies and procedures to the department.

- (c) The operation of a drug disposal program, including a drug disposal program that is authorized under federal law, shall immediately cease if a law enforcement officer, as defined in s. 165.85 (2) (c), a federal law enforcement officer, as defined in s. 175.40 (7) (a) 1., the department, or another federal or state agency notifies a designated contact person for the program that the program is in violation of any federal or state law enforceable by the officer, department, or other agency. That notification is not subject to judicial review. The program may resume operation only upon the program's receipt of written notice from the officer, department, or other agency that the program is no longer in violation of the federal or state law.
- (6) Transfer and receipt of pharmaceutical items. (a) Notwithstanding ss. 450.03 (1) and 450.11 (7) (g) and (h) and (9) (b), a person that lawfully possesses a pharmaceutical item may transfer, and it is not a crime for such a person to transfer, the pharmaceutical item to a drug disposal program if the program is authorized under sub. (2) or (3) or is authorized under federal law.
- (b) Notwithstanding s. 450.11 (7) (g) and (h) and (9) (b), a person may receive, and it is not a crime for a person to possess, a pharmaceutical item pursuant to a drug disposal program if the receipt or possession is within the scope of the program and

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the program is authorized under sub. (2) or (3) or is authorized under federal law or, if the receipt or possession is not within the scope of the program, the receipt or possession is inadvertent and the program promptly notifies an appropriate law enforcement officer of the receipt or possession and complies with any instructions the law enforcement officer provides. **Section 3.** 450.01 (23) (n) of the statutes is created to read: 450.01 (23) (n) The operation or implementation of a drug disposal program that is authorized under s. 440.255 (2) or (3) or is authorized under federal law, as defined in s. 440,255 (1) (a), or the possession or delivery of a pharmaceutical item, as defined in s. 440.255 (1) (d), within the scope of a drug disposal program that is authorized under s. 440.255 (2) or (3) or is authorized under federal law. **SECTION 4.** 450.01 (23) (o) of the statutes is created to read: 450.01 (23) (o) The possession or delivery of a prescription drug within the scope of a written authorization under s. 450.115 (3). **SECTION 5.** 450.115 of the statutes is created to read: 450.115 Drug disposal programs and authorizations. (1) In this section: (a) "Guardian" means the person named by the court under ch. 880, 2003 stats., or ch. 48 or 54 that has the duty and authority of guardianship. (b) "Personal representative" means an executor, administrator, or special administrator of a decedent's estate, a person legally authorized to perform substantially the same functions, or a successor to any of those persons. (c) "Trustee" means a person that holds in trust title to or power over property.

"Trustee" includes an original, added, or successor trustee.

(d) "Ward" means a person for whom a guardian has been appointed.

- (2) Nothing in this chapter, or rules promulgated under this chapter, prohibits any of the following:
- (a) The direct operation or implementation of a drug disposal program that is authorized under s. 440.255 (2) or (3) or is authorized under federal law, as defined in s. 440.255 (1) (a).
- (b) The transfer of a prescription drug by a person that lawfully possesses the prescription drug to a drug disposal program that is authorized under s. 440.255 (2) or (3) or is authorized under federal law, as defined in s. 440.255 (1) (a), and that accepts the prescription drug.
- (c) Subject to sub. (4), the possession of a prescription drug under a written authorization described in sub. (3).
- (3) (a) A guardian may grant written authorization to an adult who is related to the guardian's ward by blood, marriage, or adoption within the 3rd degree of kinship as computed under s. 990.001 (16), or to a domestic partner of the ward under ch. 770, for the disposal of a prescription drug that belongs to the ward.
- (b) A personal representative or a trustee may grant written authorization to an adult beneficiary, as defined in s. 701.20 (2) (b), of the estate or trust for the disposal of a prescription drug that belongs to the estate or trust.
- (c) A person who is a competent adult may grant written authorization to that person's domestic partner under ch. 770 or to another adult who is related to that person by blood, marriage, or adoption within the 3rd degree of kinship as computed under s. 990.001 (16), for the disposal of a prescription drug that lawfully belongs to that person.
- (4) A written authorization under sub. (3) is valid only to the extent permitted under federal law and only if all of the following conditions are satisfied:

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1	(a) The authorization describes with reasonable specificity each prescription
2	drug that is to be disposed of.
3	(b) The authorization is in the physical possession of the person authorized to
4	dispose of the prescription drug and each prescription drug described in the
5	authorization is, within 24 hours after the authorization is signed by the person
6	granting the authorization, transferred to a drug disposal program under s. 440.255
7	or otherwise lawfully disposed of.
8	(c) The authorization and each prescription drug to be disposed of were
9	obtained without consideration.
10	SECTION 6. Subchapter III (title) of chapter 961 [precedes 961.31] of the
11	statutes is amended to read:
12	CHAPTER 961
13	SUBCHAPTER III
14	REGULATION OF MANUFACTURE,
15	DISTRIBUTION AND, DISPENSING,
16	AND POSSESSION OF CONTROLLED
17	SUBSTANCES
18	SECTION 7. 961.32 (2) (e) of the statutes is created to read:
19	961.32 (2) (e) A person actively engaged in the direct operation or
20	implementation of a drug disposal program that is authorized under s. 440.255 (2)
21	or (3) or is authorized under federal law, as defined in s. 440.255 (1) (a).
22	<b>SECTION 8.</b> 961.335 (1) of the statutes is renumbered 961.335 (1) (a) and
23	amended to read:
24	961.335 (1) (a) Upon application the controlled substances board may issue a
25	permit authorizing a person to manufacture, obtain, possess, use, administer, or

dispense a controlled substance for purposes of scientific research, instructional
activities, chemical analysis, or other special uses, without restriction because of
enumeration. No

- (b) Except as provide in par. (c), no person shall may engage in any such activity described under par. (a) without a permit issued under this section, except that an.
- (c) 3. An individual may be who is designated and authorized to receive the a permit under this section for a college or university department, research unit, or similar administrative organizational unit, and students, laboratory technicians, research specialists, or chemical analysts under his or her supervision, may be permitted possession and use of controlled substances for these purposes, without obtaining an individual additional permit issued under this section, possess and use a controlled substance, for the purposes authorized in the permit received for the department or unit.

**Section 9.** 961.335 (1) (c) 1. and 2. of the statutes are created to read:

- 961.335 (1) (c) 1. A person who is actively engaged in the direct operation or implementation of a drug disposal program that is authorized under s. 440.255 (2) or (3) or is authorized under federal law, as defined in s. 440.255 (1) (a), may, without a permit issued under this section, obtain or possess a controlled substance for the purposes of operating and implementing the drug disposal program.
- 2. A person who is permitted under federal law to dispose of a controlled substance may, without a permit issued under this section, possess the controlled substance for the purpose of disposing of the controlled substance.

**Section 10.** 961.337 of the statutes is created to read:

961.337 Drug disposal programs. Nothing in this chapter, or rules promulgated under this chapter, prohibits any of the following:

publication.

(1) The direct operation or implementation of a drug disposal program that is
authorized under s. 440.255 (2) or (3) or is authorized under federal law, as defined
in s. 440.255 (1) (a).
(2) The transfer by the ultimate user, or by another person that lawfully
possesses the controlled substance or controlled substance analog, of a controlled
substance or controlled substance analog to a drug disposal program that has been
authorized under s. 440.255 (2) or (3) or is authorized under federal law, as defined
in s. 440.255 (1) (a), and that accepts the controlled substance or controlled substance
analog.
Section 11. Effective date.
(1) This act takes effect on the first day of the 4th month beginning after

(END)